Conflict of Interest- Sponsored Programs

Policy Number: AA-09-001

Policy Administrator: | VP of Administration & Finance and The Provost & VP for Academic

Affairs

Policy Initiator: Dean of Extension Services

Authority: Title 42 CRF Part 50 Subpart F, & Title 45 CFR Part 94 (Research

Contracts), Uniform Guidance 2 CFR 200, California Code of Regulations Title 2 Section 18755, & CSU Executive Order 890

Effective Date: January 2015

Revised Date: June 2016

Approved: President Thomas A. Cropper

Approval Signature: /s/

Purpose:

This Policy establishes the process and responsibility to comply with conflict of interest regulations related to the Principal Investigator (PI), students, and research staff engaged in sponsored programs activities.

Scope:

California State University Maritime Academy (Cal Maritime) is responsible for ensuring that Sponsored Program funding received by the university is managed and spent according to the terms and conditions of the sponsor, as well as the policies and regulations applicable to Cal Maritime. This extends to our responsibility to ensure that sponsored programs funding is expended without financial conflicts of interest.

Accountability:

The Dean of Extension Services is delegated the responsibility to ensure compliance with federal, state, and Cal Maritime regulations regarding the disclosure, filing, and resolution of conflicts of interest related to sponsored programs.

Policy:

Cal Maritime requires PIs and key personnel on a sponsored project to complete a disclosure form before expenses can be charged to an award. PIs are required to disclose a list of significant financial interests that could be reasonably expected to bias the design, conduct, or reporting of the project.

In addition, as required by the California State University(CSU) Conflict of Interest policy, Cal Maritime requires the annual completion of a Statement of Economic Interests Form 700, for all university positions whose decisions "may foreseeably have a material effect on financial interests" of the University. Some faculty and MPPs at Cal Maritime may be required to complete both a project specific disclosure form for Sponsored Programs and a statement of economic interests form for Human Resources.

For all non-NIH awards, PIs who are employed by the University must complete the CSU Ethics and Conflict of Interest Training within 6 months of receiving an award. For NIH awards, the training should be completed before expenditures are charged to the award. Subsequent training is required at least once each consecutive period of two calendar years that the award is in place.

A. Sub-Recipients

- 1. Cal Maritime requires sub-recipients to identify whether they will follow Cal Maritime's Financial conflict of interest (FCOI) policy, or if they have their own in place; if following their own FCOI policy, they must also verify that their policy complies with all appropriate regulations.
- **2.** Cal Maritime requires that the sub-recipient report identified FCOI's for its PIs within a timeframe that in turn allows Cal Maritime to report FCOIs to the appropriate funding agency.

B. Retrospective Review

If a Significant Financial Interest is discovered that was not disclosed in a timely manner by a PI or failure by Cal Maritime to review or manage an interest, the Dean of Extension Services has 60 days to determine if the disclosure constitutes a Conflict of Interest.

C. Resolution Plan

- 1. If a conflict of interest appears to be present, the campus review committee (Dean of Extension Services, PI's department administrator, and the AVP of Human Resources, Diversity & Inclusion, and Administration) shall determine what conditions or restrictions, if any, should be imposed on the research or PI in order to manage, reduce, or eliminate the conflicts.
- 2. The committee may consult with the PI and others to develop a plan to resolve any real or apparent conflict of interest issues. The committee shall then recommend that the University take one of the following actions: (1) acceptance of the award, (2) withdrawal of the proposal or disapproval of acceptance of the award, or (3) acceptance of the award subject to modifications in either the proposal or in the external affiliations or economic interests of the PI. Recommended actions to resolve conflicts may include:
 - a. Public disclosure of significant financial interests
 - **b.** Monitoring of research by independent reviewers
 - c. Modification of the research plan
 - **d.** Disqualification from participation in the portion of the project that is affected by the significant financial interest
 - e. Divestiture of significant financial interests
 - **f.** Severance of relationships that create actual or potential conflicts
- **3.** The Resolution Plan must be in writing and approved by the Provost and VP for Academic Affairs and must be implemented prior to the award being activated.
- **4.** If required by the sponsoring agency, prior to the expenditure of funds, the Dean of Extension Services will notify the sponsoring agency of the existence of an FCOI (but not the nature of the interest) and provide assurance that the conflict has been managed, reduced, or eliminated.
- 5. The PI will affirm in writing that he/she agrees to comply with the condition(s) and/or restriction(s) imposed by the Dean of Extension Services, PI's department administrator and the PI himself/herself, within ten (10) days of receiving the determination letter or management plan.

D. Documentation and Records Maintenance

Cal Maritime's HR Department will maintain records of all financial disclosures and of all actions taken to resolve financial conflicts of interest for at least <u>three years</u> beyond the termination or completion of the grant to which they relate, or until the resolution of any federal action involving those records, whichever is longer.

E. Related Documents

- 1. Disclosure of Financial Interests Certification Form
- 2. California Form 700 U-Statement of Economic Interest for Principal Investigators
- 3. Title 42 Code of Federal Regulations (CFR) Part 50 Subpart F
- 4. Title 45 CFR Part 94 (Research Contracts)
- 5. Uniform Guidance 2 CFR 200
- 6. California Code of Regulations Title 2 Section 18755
- 7. CSU Executive Order 890
- 8. CSU HR Coded Memo HR 2015-05

F. Forms

1. Disclosure of Significant Financial Interest

a. Federal Awards:

Cal Maritime uses a form entitled Disclosure of Financial Interests Related to Projects Sponsored by NSF, PHS, or other Agencies Adopting the Federal Requirements that is mandatory for all PIs who submit proposals to the National Science Foundation (NSF), the Public Health Service (PHS), or to other sponsors that have adopted the federal requirements for financial disclosure.

b. Non-Federal Awards:

Cal Maritime uses California Form 700 U (Statement of Economic Interest for Principal Investigators) for disclosure of financial interest for all non-federal sponsors. Excluding non-federal sponsors who have adopted the federal requirements for financial disclosure.

2. Disclosure Exemption Policy

- **a.** Non-governmental Entities Exempt from Disclosure requirements: PIs are not required to complete a disclosure form if their project is sponsored by a non-governmental agency listed. See "Conflict of Interest Procedures, Appendix A".
- **b.** PIs are not required to complete a disclosure form if their project is funded by internal Cal Maritime funds.

3. Conflict of Interest Form Submission Timeline

- **a.** Federal Sponsors:
 - 1. At the time of proposal submission
 - 2. Annually, during the period of the award or
 - 3. Within 30 days of discovering or acquiring a new FCOI
- **b.** Non-Federal Sponsors:
 - 1. Before final acceptance of contract or grant
 - 2. Annually, during the period of the award

4. Requirements Specific to PHS Funds

See Procedures

G. Roles and Responsibilities

1. PI:

During proposal development will submit a Disclosure of Financial Interests Form for Federal proposals or a 700U for non-federal proposals to the Dean of Extension Services or his/her designee. These forms are used to disclose a financial conflict that might affect the outcome of the funded research. The PI will also:

- a. Notify Sponsored Programs (SP) immediately of any change in disclosure
- **b.** Assist SP in obtaining disclosure forms from key project personnel and if necessary assist with obtaining verification of disclosure forms from sub-contract personnel
- **c.** Work with the Dean of Extension Services to develop a plan of action to address a conflict of interest if one exists.

- **d.** Take the Ethics and Conflict of Interest Training prior to expending any funds and per policy.
- e. Keep the original Certificate of COI Training.

2. Key Personnel:

Will submit a Disclosure of Financial Interests Form for Federal proposals or a 700U for non-federal proposals to the Dean of Extension Services or his/her designee. These forms are used to disclose a financial conflict that might affect the outcome of the funded research. This individual will:

- a. Notify SP immediately of any change in disclosure.
- **b.** Work with the Dean of Extension Services to develop a plan of action to address a conflict of interest if one exists.
- **c.** Take the Ethics and Conflict of Interest Training prior to expending any funds and per policy.
- **d.** Keep the original Certificate of COI Training.

3. Sponsored Programs (SP) staff:

- **a.** Ensure that FCOI disclosure forms are completed for all proposals and awards as required.
- **b.** Contact HR with a list of names and email addresses to setup SkillSoft Ethics and COI Training.
- c. Ensure that appropriate FCOI documentation procedures are being followed
- **d.** Identify PIs who have received non-governmental awards and verify they have completed requirements.

4. Dean of Extension Services or designee

Will perform the initial review of all Disclosures of Financial Interest and:

- **a.** Determine whether a PI's SFI is a conflict of interest.
 - 1. If a faculty member reports no financial interests, the form will be filed and no further action required.
 - **2.** If a SFI is reported, Dean of Extension Services will review the form to determine if a COI exists.
- **b.** Develop a resolution strategy with the PI to manage, eliminate, or reduce conflicts of interest.
- **c.** Take necessary action to manage FCOI's, including those of sub-recipient PIs and monitoring a PI's compliance with the established Resolution Plan through completion of the project.
- **d.** Serve as liaison to federal agencies regarding unresolved financial conflicts of interest.
- e. Participate as a member of the Conflict of Interest Resolution Committee.
- **f.** Contact the CSU Office of General Counsel when legal questions arise related to an identified conflict of interest.

5. PI's Department Administrator

Will participate as a member of the Conflict of Interest Resolution Committee.

6. CSU Office of General Counsel:

Will review the plan with the Dean of Extension Services and provide assistance with any legal questions if a plan of action to address a financial conflict of interest has legal ramifications.

7. Human Resources staff:

- **a.** Send the individual an email notification reminding them of their ethics training obligations and watch for an email from Skill Soft.
- **b.** Follow up with PI for a copy of the Certified COI Training document.

H. Definitions

1. Conflict of interest (COI):

An actual or potential interest that could directly and substantially (as determined by the Dean of Extension Services and/or his/her designee), affect the design, conduct, or reporting of funded research, or of scholarly and/or educational activities funded under external grants, contracts, or cooperative agreements. COIs can be financial (FCOI) or obligatory (OCOI) in nature.

2. Financial conflict of interest (FCOI):

A financial interest that could directly and substantially affect the design, conduct, or reporting of funded research or scholarly and/or educational activities funded under external grants, contracts, or cooperative agreements.

3. FCOI report:

Cal Maritime's report of a financial conflict of interest to a funding entity.

4. Governmental agency:

Any governmental agency that has promulgated regulations or policies requiring PI financial disclosure or requiring institutional conflict of interest policies relating to the receipt of grants or contracts.

5. Obligatory interest (OCOI):

A relationship (regardless of compensation) that involves a responsibility or commitment to an external entity, including but not limited to being a founding member of that entity, or holding a scientific advisory position, or a governing board membership.

6. Significant financial interest:

- **a.** A financial interest consisting of one or more of the following interests of the PI (and those of the PI's spouse and dependent children) that reasonably appears to be related (associated with a common idea or practice) to the PI's institutional responsibilities. The term means anything of monetary value, including, but not limited to:
 - 1. Salary or other payments for services (e.g., consulting fees or honoraria)
 - 2. Equity interest (e.g., stocks, stock options, or other ownership interests)
 - 3. Intellectual property rights (e.g., patents, copyrights, and royalties from such rights) For PIs funded by the National Science Foundation (NSF), significant financial interest includes a de minimis threshold of \$10,000.

For PIs funded by the Public Health Service (PHS), significant financial interest includes a de minimis threshold of \$5,000 for disclosure which generally applies to payments for services and equity interests. This includes any equity interest in non-publicly traded entities

- **b.** The term significant financial interest <u>does not include</u> the following types of interests:
 - 1. Salary, royalties or other remuneration from the applicant institution
 - 2. Any ownership interests in the institution, if the institution is an applicant under the Small Business Innovation Research Program or Small Business Technology Transfer Program
 - **3.** Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
 - **4.** Income from service on advisory committees or review panels for public or nonprofit entities;
 - **5.** An equity interest that, when aggregated for the PI and the PI's spouse and dependent children, meets both of the following tests: does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a 5% ownership interest in any single entity.
 - **6.** Salary, royalties or other payments that when aggregated for the PI and the PI's spouse and dependent children, are not expected to exceed \$10,000 during the next funded twelve-month period
 - 7. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the PI does not directly control the investment decisions made in these vehicles.

Procedure:

A. Requirements Specific to NSF Funds

For NSF awards, the Dean of Extension Services will inform the NSF's Office of the General Counsel if Cal Maritime is unable to satisfactorily manage a financial conflict of interest. NSF's Office of the General Counsel will conduct a review.

B. Requirements Specific to PHS Funds

1. Reporting Requirements to the NIH:

The Dean of Extension Services or his/her designee will send initial, annual and revised FCOI reports, as required by 42 CFR 50.604(h) and 42 CFR 50.605(b) to the National Institutes of Health for Cal Maritime and any sub-recipients at the following times:

- **a.** Prior to the expenditure of funds
- **b.** Within 60 days of identification of a PI new to the project
- c. Within 60 days for new, or newly identified, FCOIs for existing PIs
- **d.** Annually to provide the status of the FCOI and any changes to the management plan until completion of the project

2. Travel Reimbursements and Sponsored Travel:

PIs with PHS funding are required to disclose the occurrence of any reimbursed travel or sponsored travel related to Institutional responsibilities (including purpose of trip, sponsor/organizer, destination, and duration). Disclosure of travel reimbursements and Sponsored Travel does not include travel that is reimbursed or sponsored by a federal, state, local government agency, an Institution of Higher Education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of Higher Education.

3. Significant Financial Interest (SFI):

For PIs funded by the Public Health Service (PHS) an SFI includes a deminimis threshold of \$5,000 for disclosure, which generally applies to payments for services and equity interests. This includes any equity interest in non-publicly traded entities.

4. Training on Financial Conflicts of Interest:

PIs with PHS funding will be required to complete an online FCOI training at the following time:

Immediately, if:

- a. Cal Maritime revises its FCOI policy in such a way that it affects the requirements of PIs
- **b.** A PI is new to an Institution
- c. A PI is not in compliance with the policy or management plan

C. Reporting FCOI to PHS

- **1.** For PHS awards, the Dean of Extension Services will notify the PHS Awarding Component of the following information:
 - a. Grant/Contract number
 - **b.** Project Director (PD)/ PI or Contact PD/PI
 - c. Name of PI with FCOI
 - d. Whether FCOI was managed, reduced, or eliminated
 - e. Name of the entity with which the PI has a FCOI
 - **f.** Nature of the FCOI (i.e., equity, consulting fees, travel reimbursement, honoraria)
 - **g.** Value of the financial interest (\$0-4,999; \$5K-9,999; \$10K-19,999; amounts between \$20K-\$100K by increments of \$20K; amounts above \$100K by increments of \$50K or statement that a value cannot be readily determined)
 - **h.** A description of how the financial interest relates to PHS-funded research and the basis for the Institution's determination that the financial interest conflicts with such research.

Financial Conflict of Interest Policy - Appendix A

SPONSORS OF RESEARCH EXEMPTED FROM UNIVERSITY NON-GOVERNMENTAL ENTITY FINANCIAL DISCLOSURE REQUIREMENT

These research sponsors are approved by the University and the Fair Political Practices Commission for exemption from the University's non-governmental entity financial disclosure requirement. Principal Investigators are not required to fill out financial disclosure statements for research that is sponsored by these organizations.

All non-profit, tax-exempt educational institutions

Alzheimer's Disease & Related Disorders Association

American Academy of Dermatology American Academy of Pediatrics

American Association for the Advancement of Science

American Association for State & Local History American Association of Colleges of Pharmacy

American Association of Obstetricians & Gynecologists

American Association of Retired Persons

American Cancer Society

American Chemical Society

American College of Obstetricians & Gynecologists

American College of Radiology

American Committee for the Weizmann Institute of

Science

American Council of Learned Societies

American Diabetes Association

American Foundation for Pharmaceutical Education

American Fund for Dental Education, Inc. American Gastroenterologic Association American Health Assistance Foundation

American Heart Association
American Kidney Fund
American Library Association
American Liver Foundation
American Lung Association
American Lupus Society, The
American Nurses Foundation

American Parkinson Disease Association American Philological Association American Philosophical Society

American Red Cross

Amyotrophic Lateral Sclerosis Society of America

Arthritis Foundation

Asthma & Allergy Foundation of America

Bush Foundation, The

California Association for Neurologically Handicapped

Children

California Division of the American Cancer Society

California Heart Association California Lung Association

Cargill Foundation

Carnegie Corporation of New York

Carnegie Foundation for the Advancement of Teaching

Cerebral Palsy Foundation Chicago Community Trust, The

Childs Memorial Fund, The Jane Coffin

Christian Children's Fund

Clark Foundation, The Edna McConnell

Columbia Foundation
Commonwealth Fund, The
Cooley's Anemia Foundation
Council on Library Resources

Culpeper Foundation, Inc., Charles E.

Cystic Fibrosis Foundation

Deafness Research Foundation, The Donner Foundation, William H.

Dover Fund, Inc.

Dreyfus Foundation, Inc., The Camille & Henry Dreyfus Foundation, The Max & Victoria

Dysautonomia Foundation

Earhart Foundation

Easter Seal Research Foundation Epilepsy Foundation of America

Eye Research Institute of Retina Foundation

Fight for Sight Ford Foundation, The

Foundation for Child Development

Fuller Fund, The Anna

German Marshall Fund of the U.S.

Giannini Foundation

Grant Foundation, The William T. Guggenheim Foundation, H.F.

Guggenheim Memorial Foundation, John Simon

Haas Fund, The Walter & Elise Hartford Foundation, John A.

Haynes Foundation, The John Randolf & Dora

Hearst Foundation, William R.

Hewlett Foundation, The William & Flora

Institute for Educational Affairs

International Research & Exchanges Board

Appendix A

Japan Foundation

Johnson Foundation, The Robert Wood

Juvenile Diabetes Foundation Kade Foundation, Inc., The Max

Kaiser Family Foundation, The Henry J. Keck

Foundation, William M. Kellogg Foundation, W.K.

Klingenstein Fund, The Esther & Joseph Knights Templar Eye Foundation Kresge

Foundation, The

Kunstadter Family Foundation, The Albert Leakey Foundation, The L.S.B. Leukemia

Society

Levi Strauss Foundation Lilly

Endowment, Inc.

Luce Foundation, Inc., The Henry Lupus

Foundation of America

MacArthur Foundation, John D. & Catherine T. McKnight

Foundation, The March of Dimes

Markle Foundation, The John & Mary R. Mellon Foundation, The Andrew W. Mott Foundation, Charles Stewart Muscular Dystrophy Association Myasthenia Gravis

Foundation

National Academy of Sciences

National Collegiate Athletic Association National

Council of Teachers of English National Foundation for Ileitis & Colitis National Foundation for Infectious Diseases National Fund for Medical Education National

Geographic Society

National Head Injury Foundation National Hemophilia Foundation National Kidney Foundation National Leukemia Association National Migraine Foundation National Multiple

Migraine Foundation National Multiple Sclerosis Society National Research

Council

National Retinitis Pigmentosa Foundation National Society to Prevent Blindness

National Sudden Infant Death Syndrome Foundation

National Tuberous Sclerosis Association

Northern California Society to Prevent Blindness Noyes

Foundation, Inc., Jessie Smith Organization for Tropical Studies

Packard Foundation, The David & Lucille

Paralyzed Veterans of America Pardee Foundation, Elsa U. Peierls Foundation, Inc., The Picker

Foundation, James Population Council

Presiding Bishop's Fund for World Relief

Project HOPE

Research Corporation
Research to Prevent
Blindness Resources for the

Future, Inc.

Retirement Research Foundation Richardson Foundation, Smith Rippel Foundation, Fannie E. Rockefeller Brothers Fund Rockefeller Foundation Rosenberg Foundation

Rubin Foundation, Inc., Samuel

Runyon-Walter Winchell Cancer Fund, Damon

Sage Foundation, Russell San Francisco Foundation Scaife Foundation, Inc., Sara Schiff Foundation

Scottish Rite Schizophrenia Research Program Sherman Foundation, Nate H. Skaggs Foundation, L.J. & Mary C.

Skin Cancer Foundation Sloan Foundation, Alfred P. Social Science Research Council Spencer Foundation, The

Teagle Foundation

Tinker Foundation, Inc., The Treadwell Foundation, Nora Eccles

United Cerebral Palsy

United Scleroderma Research Foundation

U.S. Olympic Committee Webb Foundation, Del E. Weingart Foundation

Wenner-Gren Foundation for Anthropological Research,

nc.

Whitehall Foundation

Whitney Foundation, the Helen Hay

Wood Charitable Trust, W.P. Woods Hole Oceanographic Institution Zellerbach Family Fun

HR Conflict of Interest Process PI begins contract or grant proposal with Sponsored Programs. **Sponsored Programs** Sponsored PI completes 700U will notify HR once a Sponsored Programs makes or COI form at the contract or grant is Programs sends a copy of the time of proposal Yes awarded and confirm the original 700U or COI and submission and the PI has completed 700U or COI saves it in the sends it to or will complete COI form to HR. Grants folder. Sponsored training. Programs. HR receives Subsequent COI training is Within 6 months of original 700U required at least once during or COI form receiving a contract or each consecutive period of two grant PI MUST complete and schedules calendar years the award is in Is proposal COI training. employees for place. awarded? COI training. PI renews their COI or 700U No further annually during the period of the No award. This is initiated by action needed. Sponsored Programs and the

original form is sent to HR.